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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,902	10/13/1999	JOHN MCCAFFERTY	05569.0004.DVUS06	6750

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/416,902	MCCAFFERTY ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44,47,48 and 53-62* is/are pending in the application.

4a) Of the above claim(s) *53-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44, 47-48, 61-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2008 has been entered.

Status of the Claims

2. New claims 61-62 were added and claims 46 and 51-52 were canceled by the amendment filed on November 30, 2005.

The amendment to the claims received on April 2, 2007 amended claim 44 and canceled claim 45.

The supplemental amendment received on June 6, 2007 amended claim 44.

The amendment to the claims received on November 16, 2007 canceled claims 49-50.

Claims 44, 47-48, and 53-62 are currently pending.

Claims 44, 47-48, and 61-62 are currently under consideration.

Election/Restrictions

3. Applicants elected, without traverse, Group I (now claims 44, 47-48, and 61-62) in the reply filed on March 15, 2004. Claims 53-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or

linking claim. Please note: it is suggested that claims 53-60 be canceled in response to the present Office action.

Priority

4. The present application claims status as a divisional of 08/484,893 filed June 7, 1995 (now U.S. Patent 6,172,197), which is continuation of 07/971,857 filed January 8, 1993 (now U.S. Patent 5,969,108), which is a continuation of PCT/GB91/01134 filed July 10, 1991.

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) for UK 9015198.6 filed July 10, 1990; UK 9022845.3 filed October 19, 1990; and UK 9024503.6 filed November 12, 1990. The certified copies have been filed in parent Application No. 07/971,857, filed on January 8, 1993.

Invention as Claimed

6. A method of obtaining a member of a specific binding pair the method comprising: (a) providing a library of *in vitro* mutagenized nucleic acid from an existing antibody coding sequence, (b) producing a library of filamentous bacteriophage particles displaying a population of specific binding pair members which comprise a binding domain of an immunoglobulin each particle containing nucleic acid from the library of *in vitro* mutagenized nucleic acid from an existing antibody coding sequence, (c) contacting the library of filamentous bacteriophage particles with a desired epitope, and (d) separating particles displaying specific binding pair members comprising a binding domain which binds to said epitope wherein the specific binding pair members are Fabs and variations thereof.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on July 17, 2008 is being considered by the examiner.

Claim Objections

8. Claims 44, 47-48, and 61-62 are objected to because of the following informalities:

A. *in vitro* should be in italics (see lines 3 and 7 of claim 44),

B. nucleic acid should be plural (i.e. nucleic acids; see lines 3 and 7 of claim 44),

C. displaying should read "displaying on the surface" (see lines 5 and 11 of claim 44),

D. particle should read "filamentous bacteriophage particle" (see lines 7 and 11 of claim 44, line 3 of claim 47, line 3 of claim 48, and line 3 of claim 61),

E. nucleic acid should read "a nucleic acid sequence" (see line 7 of claim 44, line 3 of claim 47, lines 1 and 3 of claim 48, the second "nucleic acid" in line 5 of claim 48, lines 1 and 3 of claim 61, and the second "nucleic acid" in line 5 of claim 61),

F. nucleic acid should read "the nucleic acid sequence" (see line 5 of claim 47, the first "nucleic acid" in line 5 of claim 48, last line of claim 61, and line 3 of claim 62), and

G. the nucleic acid should read "the nucleic acid sequence" (see line 5 of claim 61).

Appropriate correction is required.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 44, 47-48, and 61-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,555,313. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention claimed in U.S. Patent 6,555,313 are drawn to methods of obtaining a member of a specific binding pair.

For present claims 44, 47-48, and 61-62, U.S. Patent 6,555,313 claim a method of obtaining a member of a specific binding pair comprising (a) providing a library of filamentous bacteriophage containing nucleic acid with sequence derived from human species unimmunized with a human self antigen (i.e. nucleic acid from an existing antibody coding sequence) wherein the nucleic acid encodes Fab, can be synthetic, and can be modified via addition, deletion, substitution, etc. (i.e. *in vitro* mutagenized; see claims 9, 11-12, and 17-18), (b) displaying on the surface of the filamentous bacteriopahge a specific binding pair (i.e. producing a library of filamentous bacteriopahge particles), (c) selecting via binding with a human self antigen one or more specific binding pair members (i.e. contacting and separating), and (d) nucleic acid from one or more filamentous bacteriophage is taken and used to provide encoding nucleic acid in a

further method to obtain an individual specific binding pair member, a mixed population of specific binding pair members, or an encoding nucleic acid (i.e. obtaining/producing; see claims 1-22).

11. Claims 44, 47-48, and 61-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 5,885,793. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention claimed in U.S. Patent 5,885,793 are drawn to methods of obtaining a member of a specific binding pair.

For present claims 44, 47-48, and 61-62, U.S. Patent 5,885,793 claim a method of obtaining a member of a specific binding pair comprising (a) providing a library of filamentous bacteriophage containing nucleic acid with sequence derived from a human unimmunized with a self antigen (i.e. nucleic acid from an existing antibody coding sequence) wherein the nucleic acid encodes Fab, can be synthetic, and can be modified via addition, deletion, substitution, etc. (i.e. *in vitro* mutagenized; see claims 9, 11, and 16-17), (b) displaying on the surface of the filamentous bacteriopahge a specific binding pair (i.e. producing a library of filamentous bacteriopahge particles), (c) selecting via binding with a self antigen one or more specific binding pair members (i.e. contacting and separating), and (d) nucleic acid from one or more filamentous bacteriophage is taken and used to obtain an individual specific binding pair member, a mixed population of specific binding pair members, or an encoding nucleic acid (i.e. obtaining/producing; see claims 1-41).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

September 16, 2008